

**REMARKS**

Applicant respectfully requests reconsideration of the rejections in view of foregoing amendments and the reasons that follow.

***I. Status of the Claims***

Claim 44 is currently amended. Claim 47 is canceled. Support for the amendment to claim 44 can be found in previously presented claim 47 and the originally filed specification on pages 12 and 13. No new matter is introduced.

After the entry of this amendment, claims 44-46, 48-50, 53 and 54 are pending.

***II. Rejections under 35 U.S.C. §103(a)***

The Examiner rejects claims 44-50, 53, and 54. (Office Action Summary) However, the Examiner's discussion is directed to claims 49 (which Applicant believes should be 44) and 54 only. Specifically, the Examiner rejects claims 44 and 54 as being obvious over U.S. Patent No. 4,142,526 to Zaffaroni. (Office Action, page 2)

***A. Finality of the Rejection***

The Examiner makes the instant Office Action final. Applicant respectfully submits that the finality is improperly made because the Examiner did not raise the obviousness rejection which could have been raised in the last office action.

Additionally, the Examiner does not address the patentability of the claims other than claims 44 and 54 on the new ground.

Applicant respectfully requests the withdrawal of the finality.

***B. Merits of the Rejection***

Applicant traverses the rejection. Zaffaroni cannot render claims 44 and 54 obvious.

Claim 44 as amended recited additional feature "mixing a therapeutic drug with the copolymer composition to allow the drug uniformly dispersed in the copolymer

composition, wherein the drug concentration is 5% to 20% by weight” which Zaffaroni fails to teach or suggest.

Zaffaroni describes an osmotic device for releasing a useful agent, which is comprised of a semi-permeable wall surrounding and forming a compartment as means for containing a useful agent and having a passageway for releasing the agent. *See* Abstract. The coating on the wall can be made of poly(carboxylic acids) prepared by copolymerizing unsaturated carboxylic acids with a polymerizable hydrocarbon. *See* Col. 19, ll. 46-50. Zaffaroni does not in anyway describe a method comprising a step of mixing a therapeutic drug with the copolymer composition to allow the drug uniformly dispersed in the copolymer composition.

Zaffaroni clearly describes that the useful agent is contained in the compartment surrounded by the wall and the drug is not in anyway dispersed in the coating of the wall in the sense as claimed. In contrast, in the presently claimed invention, the drug is uniformly dispersed in the copolymer coating rather than contained in a compartment surrounded by a wall. Indeed, Zaffaroni **teaches away** from claim 44.

Furthermore, Zaffaroni does not in anyway suggest that the carboxylic acid comonomer content is 5% - 50 wt %. The Examiner asserts that the carboxylic acid comonomer content recited in claim 44 is a result of discovering the optimum or workable ranges from the general conditions disclosed in prior art. Applicant traverses.

Zaffaroni teaches a copolymer wherein the content of carboxylic acid content must be over 50% by weight. This range does not overlap with the range recited in claim 44, thus does not provide a general condition for optimization.

In the presently claimed invention, higher ethylene co-monomer content is desirable because it insures sufficient elongation of the coating to accommodate the strain associated with stent expansion. *See* Page 10, ll. 10-12. In contrast, in Zaffaroni, higher unsaturated hydrocarbon co-monomer content is not desirable because its hydrophobic nature retards the transport of drugs which tend to be functionalized and have some hydrophilic character; rather higher carboxylic acid content is desirable because its hydrophilic nature allows body fluid to permeate through so the useful agent can be

dissolved and diffuse. Thus Zaffaroni **teaches away** from increasing the unsaturated hydrocarbon co-monomer content.

Zaffaroni cannot render claim 44 obvious. At least for the same reason, Zaffaroni cannot render dependent claims 45-46, 48-50, 53 and 54 obvious.

Additionally, regarding claim 54, Zaffaroni does not in anyway suggest applying a coating of Zaffaroni on a stent. As discussed in the specification, a coating having lower unsaturated hydrocarbon co-monomer content as in Zaffaroni causes insufficient elongation resulting in cracks. *See* Page 10, ll. 6-12. Thus, Zaffaroni cannot render claim 54 obvious.

Applicant respectfully requests the reconsideration and withdrawal of the rejection on this ground.

**CONCLUSION**

Based on the above amendments and remarks, this application is believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. **07-1850**. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. **07-1850**.

Respectfully submitted,

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